

PATENT  
0040562-0020  
(formerly KM40562-20)

- III. Claims 37-40, drawn to an assay system; and
- IV. Claim 44, drawn to a method of assay.

The Examiner asserted that the inventions defined by Groups I-IV are unrelated and patentably distinct. Specifically, the Examiner argued that (i) the apparatus of Group II requires an electrode which is not required in the apparatus of Group I; (ii) the assay system of Group III requires a cartridge receptacle which is not required in the apparatus of Group I; (iii) the method of Group IV does not recite using the apparatus of Group I; (iv) the assay system of Group III requires a cartridge receptacle which is not required in the apparatus of Group II; (v) the method of Group IV does not recite using the apparatus of Group II; and (vi) the method of Group IV does not recite using the assay system of Group III.

Applicants respectfully traverse the restriction requirement for the reasons below.

First, Applicants would like to take this opportunity to draw the Examiner's attention to what may have been an inadvertent error. Claim 33 and claims which depend therefrom (claims 34-36) were restricted to Group II, instead of Group I, due to the requirement for an electrode. Page 2 of the Official Action states: "inventions I and II are unrelated. . . . The apparatus of group II requires an electrode which is not required in group I." Claim 33 does not, in fact, recite an electrode. Therefore, restriction to Group I would be more appropriate.

Further, Groups I-IV are merely different embodiments of a single inventive concept for which a single patent should issue. The Groups of claims identified in the Office Action are not distinct inventions, but rather are an intricate web of knowledge and continuity of effort which merit examination of all claims in a single application.

PATENT  
0040562-0020  
(formerly KM40562-20)

First, the claims of Group I relate to an apparatus used in a binding assay. However, claims of narrower scope, also directed to an apparatus for carrying out a binding assay, i.e., claims 13-36, were separated from the other apparatus claims and assigned to Group II. The Examiner justifies this restriction by asserting that the claims of Group II require an element that is not required in the claims of Group I. However, this is not an adequate justification for restricting the claims.

The proper bases for restriction of inventions are set forth in M.P.E.P § 806 *et seq.* According to M.P.E.P § 806, the general principles for determining if a restriction is warranted include: (1) "where inventions are independent (i.e., no disclosed relation therebetween), restriction to one thereof is ordinarily proper, . . . though a reasonable number of species may be claimed when there is an allowed . . . claim generic thereto . . . [(2)] Where inventions are related as disclosed but are distinct as claimed, restriction may be proper. . . . [and (3)] Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper." Further, § 806.03 provides that if the claims of an application define the same essential characteristics of a single disclosed embodiment, restriction should never be required.

M.P.E.P. § 806.04, which was relied on by the Examiner, defines independent inventions and provides, in pertinent part:

If it can be shown that the two or more inventions are in fact independent, applicant should be required to restrict the claims presented to but one of such independent inventions. For example:

1. Two different combinations, not disclosed as capable of use together, having different modes of operation, different functions or different effects are independent. . . .

PATENT  
0040562-0020  
(formerly KM40562-20)

2. Where the two inventions are process and apparatus, and the apparatus cannot be used to practice the process or any part thereof, they are independent. . . .

3. Where species under a genus are independent, for example, a genus of paper clips having species differing in the manner in which a section of the wire is formed in order to achieve a greater increase in its holding power (emphasis added).

Applicants respectfully submit that the apparatus claims of Group II are merely narrow embodiments of those claimed in Group I and should not be restricted, based on the foregoing guidelines. The Examiner essentially argues that the claims of Groups I and II have different modes of operation, different functions or different effects. This is simply not the case. Claim 5, for example, refers to an apparatus for use in carrying out a binding assay, comprising (a) a cell and (b) means for sonicating the contents of the cell. Claim 13, which has been assigned to Group II because it is allegedly unrelated to claim 5, relates to an apparatus for use in a binding assay, comprising (a) a cell which includes a working electrode and (b) means for sonicating the contents of the cell. The only difference between claims 5 and 13 is the inclusion of an additional restriction on the cell. However, the apparatus still contains the same essential elements, i.e., a cell and sonicating means, and the Examiner has not established how the apparatus of claims 5 and 13 have different modes of operation, different functions or different effects. It is respectfully submitted that the list provided in M.P.E.P. § 806.04, which is relied on by the Examiner, does not include different modes of operation, different functions, different effects, or additional elements, as the Examiner appears to suggest. Moreover, as stated above, M.P.E.P. § 806.03 provides that if the claims of an application define the same essential characteristics of a single disclosed embodiment, restriction should never be required. Therefore, at a minimum, Applicants respectfully submit

PATENT  
0040562-0020  
(formerly KM40562-20)

that the apparatus claims of Group II should be grouped together with the claims of Group I because they merely represent narrower embodiments of those claimed in Group I.

Even assuming *arguendo* that Groups I-IV represent distinct inventions, Applicants submit that a search of the subject matter of each group would not be a serious burden on the Examiner. The M.P.E.P. §803 (Sixth Edition, Rev. 2, July 1996) states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

It is respectfully submitted that a search of the prior art related to binding assays will necessarily uncover art directed to apparatus' and methods for conducting such assays. Thus, in addition to those reasons set forth above for reconsideration of the restriction requirement, it is also urged that the prior art uncovered by an adequate search of the claims of Group I will necessarily uncover the art related to the claims of Groups II-IV. Applicants respectfully submit that to conduct such a search would not be unduly burdensome; instead, the examination of all of the claims will be completed in an more efficient manner.

In view of the foregoing remarks and in the interest of efficiency, reconsideration and withdrawal of the requirement for restriction are requested. However, in an effort to fully respond to the restriction requirement, Applicants provisionally elect the claims defined by Group I for prosecution in the present application.

PATENT  
0040562-0020  
(formerly KM40562-20)

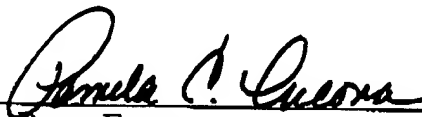
CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims are in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

WHITMAN BREED ABBOTT & MORGAN LLP  
200 Park Avenue, New York NY 10166  
Attorneys for Applicants

By: \_\_\_\_\_



Barry Evans  
Reg. No. 22,802  
George B. Snyder  
Reg. No. 27,675  
Pamela C. Ancona  
Reg. No. 41,494  
(212) 351-3000